DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office
d1598b

297 Plus Park Blvd.
Nashville, TN 37217

December 6, 1996

Rec'd 12/5/96

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

FACILITY ID #149617

WARNING LETTER-97-NSV-01

Debbie Spivey, Technical Director
Baptist Health Center - Centerpoint
1160 Huffman Road
Birmingham, AL 35215

Dear Ms. Spivey:

Your facility was inspected on November 22, 1996 by a representative of the State of Alabama, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

LEVEL 1

Records indicate that there was no medical physicist survey done for the x-ray system: [redacted]

The specific deficiency noted above previously appeared on the List of Observations sent to you by the surveyor. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to promptly correct this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct the violation noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, C.S.O., at 615/781-5380, extension 144.

Sincerely,

Raymond K. Hedblad

Raymond K. Hedblad
Director, Nashville District

RKH/ks

cc: State of Alabama, Div. of Rad. Control